

AMENDMENTS TO THE CLAIMS

1. (Currently Amended). An orally dissolving, hard boiled, dosage form useful for transmucosal oral administration of a nicotine active, comprising:
- a) a glassy matrix comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure;
 - b) a water soluble gelling gum in an amount sufficient to provide an oral dissolution rate of said glassy matrix such that a desired amount said nicotine active agent is delivered via the oral mucosa prior to ingestion into the stomach; and
 - c) said from about 0.5mg to about 5 mg of nicotine active per dose, at least 50% of which is delivered via the oral mucosa prior to ingestion into the stomach;

wherein said nicotine active agent is substantially contained within said glassy matrix.

2. (Currently Amended). The dosage form of claim 1 further comprising one or more ~~wherein said active agents is one or more~~ selected from the group consisting of drugs, cold agents, cough agents, throat agents, vitamins, zinc, menthol, eucalyptus, hexylresorcinol, caffeine, tooth whitening agents, anti-plaque agents, breath freshening agents and nicotine.

3. (Cancelled).

4. (Original). The dosage form of claim 1 wherein said water soluble gelling gum is one or more selected from the group consisting of xanthan gum, guar gum, gum arabic, alginates and carageenan.

5. (Original). The dosage form of claim 4 wherein said gum is xanthan gum.

6. (Cancelled).

7. (Currently Amended). The dosage form of claim 16 wherein at least 75% of said nicotine active is delivered via the oral mucosa.

8. (Previously Amended). The dosage form of claim 1 wherein said gum is present in an amount sufficient to provide that said dosage form dissolves orally over a period of about 10 to 15 minutes.

9. (Previously Amended). The dosage form of claim 1 wherein said water soluble gelling gum is present in an amount of from about 0.5 to about 5.0 percent by weight.
10. (Previously Amended). The dosage form of claim 9 wherein said water soluble gelling gum is present in an amount of from about 1.0 to about 4.0 percent by weight.
11. (Previously Amended). The dosage form of claim 10 wherein said water soluble gelling gum is present in an amount of from about 1.0 to 3.5 percent by weight.
12. (Previously Amended). The dosage form of claim 1 wherein the sugar alcohol comprises a mixture of 1,6-GPS (6-O- α -D-glucopyranosyl-D-sorbitol) and 1,1-GPM (1-O- α -D-glucopyranosyl-D-mannitol) in a weight ratio of from about 99:1 to about 1:99.
13. (Previously Amended). The dosage form of claim 1 comprising at least about 50% of the sugar alcohol, based on the weight of the dosage form.
14. (Previously Amended). The dosage form of claim 13 comprising at least about 70% of the sugar alcohol mixture, based on the weight of the dosage form.
15. (Previously Amended). The dosage form of claim 14 comprising at least about 85% of the sugar alcohol mixture, based on the weight of the dosage form.
16. (Cancelled).
17. (Previously Amended). The dosage form of claim 1 wherein the nicotine active is selected from nicotine oil, nicotine bitartrate, nicotine polacrilex and combinations thereof.
18. (Cancelled).
19. (Previously Amended). The dosage form of claim 12 wherein the sugar alcohol comprises a mixture of 1,6-GPS and 1,1-GPM in a weight ratio of from about 70:30 to about 30:70.

20. (Previously Amended). The dosage form of claim 12 wherein the sugar alcohol comprises a mixture of 1,6-GPS and 1,1-GPM in a weight ratio of from about 60:40 to about 40:60.

21. (Previously Amended). The dosage form of claim 12 wherein the sugar alcohol mixture is ISOMALT.

22. (Previously Amended). The dosage form of claim 1 further comprising a buffer in an amount effective to provide an alkaline mouth saliva pH.

23. (Previously Amended). The dosage form of claim 22 wherein the buffer is selected from sodium carbonate, sodium bicarbonate, calcium carbonate, potassium carbonate, potassium bicarbonate, sodium phosphate dibasic, sodium phosphate tribasic, potassium phosphate dibasic, potassium phosphate tribasic, and combinations thereof.

24. (Previously Amended). The dosage form of claim 23 wherein the buffer is selected from sodium carbonate, potassium carbonate, and combinations thereof.

25. (Previously Amended). The dosage form of claim 1 wherein the glassy matrix further comprises from about 1% to about 20%, based on the weight of the dosage form, of one or more compounds selected from the group consisting of sucrose, sorbitol, and xylitol.

26. (Currently Amended). The dosage form of claim 13 further comprising a non-pharmacological component for providing a sensory signal effective to provide rapid nicotine craving relief.

27. (Currently Amended). The dosage form of claim 13 wherein the dosage form is a lozenge.

28. (Currently Amended). A method of reducing nicotine cravings comprising orally administering a dosage form of claim 13 to a person in need of nicotine craving reduction.

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29. (Previously Amended). The method of claim 28 wherein a nicotine active blood plasma concentration of at least about 6 ng/ml is achieved after starting oral administration of the dosage form.

30. (Previously Amended). The method of claim 29 wherein a sustained nicotine active blood plasma concentration of from about 6 ng/ml to about 35 ng/ml is achieved after starting oral administration of the dosage form.

31. (Currently Amended). A method of reducing tobacco usage comprising orally administering a dosage form of claim 13 to a person in need of reducing tobacco usage.

32. (Cancelled).

33. (Cancelled).

34. (Newly presented). The dosage form of claim 1 wherein the dosage form provides a nicotine active blood plasma concentration of at least about 6ng/ml after starting oral administration of the dosage form.